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OCT 15 2012

Smith & Nephew, Inc.

510k Summary of Safety and Effectiveness

Redapt® Revision Femoral System

Contact Person and Address
Natalie P. Williams
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7135 Goodlett Farms Parkway
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Date of Summary: 6/1/12

Name of Device: Smith & Nephew Redapt® Revision Femoral System
Common Name: Femoral Hip Prosthesis
Device Classification Name and Reference: 21 CFR 888.3353 Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis
Device Class: II
Panel Code: Orthopaedics/87 MEH, LZO

Device Description

The Redapt® Revision Femoral System is comprised of a stem, modular neck, and modular sleeve component. The components of the revision hip system modularly connect together to form the complete Redapt® Revision Femoral System construct. Subject of this Abbreviated premarket notification are the Redapt® Modular Sleeved Revision Hip Stems and size 26/27 Modular Sleeves. The Modular Sleeved Revision Hip Stem is a modification of the MDF Revision Hip Stem cleared via premarket notification K081124. The Modular Sleeved Revision Hip Stem is a straight, tapered, distally fixed, modular stem. The subject device is manufactured from titanium alloy (Ti-6Al-4V), has a grit-blast finish, and is available in lengths of 240mm and 300mm in sizes 11-27. The Modular Sleeved Revision Hip Stems has a modular 12/14 female neck taper that mates with the cobalt chrome modular necks previously cleared in premarket notification K081124.

The size 26/27 Modular Sleeves are line additions to the Modular Sleeves cleared in K081124. The subject devices lock onto the proximal end of the stem to aid in proximal fixation. The size 26/27 Redapt® Modular Sleeves are identical in design to the current modular sleeves cleared by K081124 and are also offered in the same small, medium, and large cone sizes. The subject devices are proportionally larger to accommodate the size 26/27 stems. The subject devices contain the Smith & Nephew Stiktite coating. A Hydroxylapatite (HA) coating will be applied to the Stiktite coated areas of the size 26/27 Redapt® Modular Sleeves.

Indications for Use

Hip components are indicated for individuals undergoing primary and revision surgery where other treatments or devices have failed in rehabilitating hips damaged as a result of trauma or noninflammatory degenerative joint disease (NIDJD) or any of its composite diagnoses of osteoarthritis, avascular necrosis, traumatic arthritis, slipped capital epiphysis, fused hip, fracture of the pelvis, and diastrophic variant.

Hip components are also indicated for inflammatory degenerative joint disease including rheumatoid arthritis, arthritis secondary to a variety of diseases and anomalies, and congenital dysplasia; treatments of nonunion, femoral neck fracture and trochanteric fractures of the proximal femur with head involvement

that are unmanageable using other techniques; endoprosthesis, femoral osteotomy, or Girdlestone resection; fracture-dislocation of the hip; and correction of deformity.

Smith & Nephew Redapt® Revision Femoral System components are intended for single use only and are to be implanted without bone cement.

Performance Data

Performance testing has been conducted for the subject devices in accordance with the following guidance documents:

- *Non-Clinical Information for Femoral Stem Prostheses*, dated September 2007
- *Draft Guidance Document for Testing Non-Articulating, "Mechanically Locked," Modular Implant Components*, dated May 1995
- *Guidance Document for Testing Orthopaedic Implants with Modified Metallic Surfaces Apposing Bone or Bone Cement*, dated April 1994
- *Calcium Phosphate (Ca-P) Coating Draft Guidance Document for Preparation of FDA Submissions for Orthopaedic and Dental Endosseous Implants*, dated February 1997

Environmental corrosion fatigue, pre-fatigue and post-fatigue pull-off, and fatigue strength testing were performed. The range of motion of the Modular Sleeved Revision Hip Stem was also evaluated. A review of the testing and analysis has demonstrated that there are no new issues related to the safety or effectiveness of the subject devices. Clinical data was not needed to support the safety and effectiveness of the subject devices.

Substantial Equivalence Information

The materials, intended use, indications for use, sterilization, and overall design of the Smith & Nephew Redapt® Modular Sleeved Revision Hip Stems and size 26/27 Modular Sleeves are substantially equivalent to the MDF Revision Hip Stems and modular sleeves cleared by premarket notification K081124. Giving consideration to the device modifications described in the Device Description section, no changes have been made to the overall design philosophy, intended use, and material choices when compared to the predicate devices. A comparison of the subject devices to the predicate devices is provided in Table 1 below.

Table 1: Comparison of the Redapt® Hip Stems and Modular Sleeves to Predicate Devices

Design Features	Device Names	
	Subject Smith & Nephew Redapt® Hip Stems and Modular Sleeves	**Smith & Nephew MDF Revision Hip Stem System (K081124)**
Similar Indications for Use/Intended Use	Yes	Yes
Similar Sterilization	Yes	Yes
Femoral Stems		
Size Offering	11-27	11-25
Stem Lengths (mm)	240mm; 300mm	240mm; 300mm
Stem Material	Ti-6AL-4V per ASTM F1472	Ti-6AL-4V per ASTM F1472
Grit-blast Finish	Yes	Yes
Fluted Tapered Stem	Yes	Yes
Neck Taper	12/14	12/14
Cobalt Chrome Modular Necks	Yes	Yes
Modular Sleeves	**Subject Stiktite Plus HA Coated Modular Sleeves**	**Stiktite Plus HA Coated Modular Sleeves (K081124)**
Size Offering	Size 26/27 Small, Medium, and Large	Sizes 11-25 Small, Medium, and Large
Materials		
Substrate	Ti-6Al-4V per ASTM F1472	Ti-6Al-4V per ASTM F1472
Stiktite Coating	CP Ti per ASTM F 67	CP Ti per ASTM F 67
HA Coating	HA Coated per ASTM F1185	HA Coated per ASTM F1185

Conclusion

This Abbreviated 510(k) Premarket Notification is being submitted to request clearance for the Redapt® Modular Sleeved Revision Hip Stems and size 26/27 Modular Sleeves. Based on the similarities to the predicate devices, the devices are substantially equivalent to the femoral stem and modular sleeve components currently marketed under K081124.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Smith and Nephew, Incorporated
% Ms. Natalie P. Williams
Senior Regulatory Affairs Specialist
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Cordova, Tennessee 38016

OCT 15 2012

Re: K121627
Trade/Device Name: Smith and Nephew Redapt• Revision Femoral System
Regulation Number: 21 CFR 888.3353
Regulation Name: Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis
Regulatory Class: Class II
Product Code: MEH, LZO
Dated: September 28, 2012
Received: October 1, 2012

Dear Ms. Williams:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K121627 (pg 1/1)

Device Name: Smith & Nephew Redapt® Revision Femoral System

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Prescription Use (Part 21 CFR 801 Subpart D) X AND/OR Over-The-Counter Use (21 CFR 807 Subpart C) _____

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

K Lamb

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

for

510(k) Number K121627